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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,319	01/25/2005	Stanley George Bonney	PG4886-B USW	9220

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GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, MAI B482
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
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3771

NOTIFICATION DATE	DELIVERY MODE
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08/05/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM
LAURA.M.MCCULLEN@GSK.COM
JULIE.D.MCFALLS@GSK.COM

Office Action Summary	Application No. 10/522,319	Applicant(s) BONNEY ET AL.	
	Examiner KRISTEN C. MATTER	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/25/05 and 3/6/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to because figures in which multiple elements are shown (1c and 5) must include a connection means (bracket, dashed line, etc.) indicated how the parts are related so that they are not viewed as separate figures.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the meter and metering cavity chamber (particularly how it moved from a first to second position) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 19 and 20 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer back to a previous claim in the alternate only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 1, it appears a word is missing from the phrase “wherein the or” making it unclear as to what is included in the limitation of the metering means being movable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-17, 21-23, 25-29, 31-34, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Trueba (US 6,684,880).

Regarding claims 1, 25, and 26, Trueba discloses an inhaler with first and second medicament containers (50-56) having first and second release means (40-46) that are kept

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separate from each other until the point of release for delivery and an electronic control system (100) for controlling the release of the contents of the containers.

Regarding claims 2 and 32, Trueba discloses that the containers can contain different medicaments (column 3, line 1).

Regarding claims 4 and 5, Trueba discloses that the release means can be operated independently or together by the controller (column 4, line 65-column 5, line 15 and column 11, lines 1-5).

Regarding claim 6, Trueba discloses that the containers can be removable (column 4, lines 40-45).

Regarding claim 7, Trueba discloses input means (104).

Regarding claims 8 and 9, Trueba discloses an integral diagnostic system (column 11, lines 30-35).

Regarding claim 10, the computer (115) can be considered the diagnostic system that is separate from the dispenser.

Regarding claims 11 and 12, Trueba discloses that the device is programmable (and therefore inherently has memory for storage, a transmitter (column 12, lines 15-20), and microprocessor 100).

Regarding claims 13 and 14, Trueba discloses displays (105) and keypads (on both the dispenser and remote computer) for user input and data display to the system.

Regarding claim 15, Trueba discloses a data link for communicating a local data store the electronic data management system (column 12, lines 10-20).

Regarding claims 16 and 17, Trueba discloses that the medicament is metered from the reservoir (column 11, lines 1-3). The cavity from which the medicament is released from the container can be considered a metering cavity.

Regarding claim 21, the release means disclosed by Trueba allows a user to vary the amount of product released from each container (column 11, lines 39-40).

Regarding claim 22, the device of Trueba also allows a user to vary the time release of medicament (column 11, lines 48-49).

Regarding claim 23, Trueba discloses that the display can indicate the remaining doses and therefore inherently has an actuation indicator (column 7, lines 4-5).

Regarding claim 27, Trueba discloses a single outlet (35) for delivery of the medicine to the respiratory tract.

Regarding claims 28, 29, and 31, Trueba discloses a pressure sensor for sensing the inward breath of a patient in order to release the medicament for inhalation (column 6, lines 40-50).

Regarding claims 33 and 34, Trueba discloses a variety of different drugs for use in the containers including bronchodilators and steroids (column 4, lines 15-20).

Regarding claim 38, Trueba discloses a method of treating a respiratory disorder by administering an effective amount of medicament from a dispenser with the same structure as claimed in claim 1 as discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 24, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trueba.

Regarding claim 3, Trueba discloses multiple containers. To the extent, if any, that Trueba is silent as to there being only two containers, examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to have used only two containers in order to treat respiratory diseases with a combination therapy of two medicaments. In addition, it appears as though the device disclosed by Trueba would perform equally well with only two containers.

Regarding claim 24, Trueba is silent as to how the actuations are identified. However, absent a critical teaching and/or showing of unexpected results from using the claimed actuation sensors, examiner contends it would have been obvious to one of ordinary skill in the art at the time of the invention to have used one of the claimed actuation sensors in the device of Trueba for determining the remaining doses (i.e., for the manually activating embodiment, pressure sensors are well known for determining an actuation occurrence). In addition, it appears as though the device disclosed by Trueba would perform equally well with any of the claimed actuation sensors.

Regarding claims 35 and 36, Trueba discloses a variety of different drugs for use in the containers including bronchodilators and steroids (column 4, lines 15-20) but is silent as to the specific bronchodilator and anti-inflammatory. However, absent a critical teaching and/or a showing of unexpected results from using the specifically claimed medicaments, examiner contends it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to have used the well known and commonly used claimed medicaments in the device of Trueba for treating various respiratory disorders with inhalation therapy. Furthermore, it appears as though the device of Trueba would perform equally well if used with the claimed medicaments.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trueba as applied to claims 1, 2, 4-17, 21-23, 25-29, 31-34, and 38 above, and further in view of Ivri et al. (US 6,640,804). Trueba is silent as to the metering chamber being movable into fluid communication with the reservoir. However, Ivri et al. discloses a valve with a metering chamber for an inhaler that moves from a first position (Figure 15) in which medicament from the reservoir fills the metering cup to a second position (Figure 16) in which the dose is made available to the patient for inhalation. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have replaced the container and/or metering means of Trueba with the container and/or metering means of Ivri et al. in order to precisely meter out a desired dosage of medicament for each container. Furthermore, it appears as though the device of Trueba would perform equally well if a liquid medicament were used and/or if the movable metering chamber of Ivri et al. were used in place of the disclosed metering means.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trueba as applied to claims 1, 2, 4-17, 21-23, 25-29, 31-34, and 38 above, and further in view of Rand (US 2002/0189612). Trueba is silent as to a breath-movable element. However, Rand discloses that it is well known to have breath movable elements for determining when a patient is inhaling in an inhaler (paragraphs 0090-0091). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used a breath sensor with a breath movable element as taught by Rand in the device of Trueba for determining when a patient is inhaling in order to actuate medicament release. Furthermore, it appears as though the device of Trueba would perform equally well with a breath movable element.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-36 and 38 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35 and 37 of copending Application No. 10/522,324. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claims and the instant claims are minor and obvious from each other. For example, the instant claim 1 is a broader version of the copending claim 1 (i.e. the instant claim 1 does not include the structural element of at least one actuation indicator as in the copending claim 1). In the instant claim 1, the structural elements are included in (or obvious in) the copending claim 1. Any infringement over the copending application would also infringe over the instant claims. Hence, the instant claims 1-36 and 38 do not differ from the scope of the copending claims 1-35 and 37.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-36 And 38 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/502,405. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claims and the instant claims are minor and obvious from each other. For example, the instant claim 1 is a broader version of the copending claim 1 (i.e. the instant claim 1 does not include the structural element of the specific medicaments as in the copending claim 1). In the instant claim 1, the structural elements are included in the copending claim 1. Any infringement over the copending application would also

infringe over the instant claims. Hence, the instant claims 1-36 and 38 do not differ from the scope of the copending claims 1-37.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-36 and 38 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 9-22 of copending Application No. 10/523,121. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claims and the instant claims are minor and obvious from each other. For example, the instant claim 1 is a broader version of the copending claim 1 (i.e. the instant claim 1 does not include the structural element of the mechanically coupled release means as in the copending claim 1). In the instant claim 1, the structural elements are included (or obvious in) in the copending claim 1. Any infringement over the copending application would also infringe over the instant claims. Hence, the instant claims 1-36 and 38 do not differ from the scope of the copending claims 1-7 and 9-22.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771